Section 5: 510(k) Summary

K070749
OCT 24 2007

Device Information:

Category	Comments
Sponsor:	Estech 2603 Camino Ramon. Suite 100 San Ramon, CA 94583 Tel: 925-866-7111
Correspondent Contact Information:	Craig Coombs Coombs Medical Device Consulting 1193 Sherman Street Alameda, CA 94501 Tel: 510-337-0140 Fax: 510-337-0416
Device Common Name:	Vessel Dilators
Device Classification & Code:	Class II, DRE (21 CFR 870.1310)
Device Classification Name:	Vessel dilator for percutaneous catheterization
Device Proprietary Name:	ESTECH Percutaneous Dilator Insertion Kit

Predicate Device Information:

Predicate Devices:	Vessel Dilators (K963388)
Predicate Device Manufacturers:	Maxxim Medical, Inc. a division of Argon Medical Devices
Predicate Device Common Name:	Vessel dilator for percutaneous catheterization
Predicate Device Classification:	21 CFR 870.1310
Predicate Device Classification & Code:	Class II, DRE

b. Date Summary Prepared
9 March 2007

c. Description of Device
The Estech Percutaneous Dilator Insertion Kit is a sterile, single-use, physicians convenience kit to dilate blood vessels to allow for the insertion of large diameter catheters. The kit consists of seven pieces:

1. One 18 gage stainless steel insertion needle
2. One stainless steel 0.035" or 0.038" guidewire
3. Five plastic dilators, sized 8, 12, 16, 20 and 24 Fr.

These pieces may be packaged, sterilized and sold separately.

d. Intended Use

The ESTECH Percutaneous Insertion Dilator Kit is intended for use in surgical procedures to aid in percutaneous insertion of a catheter or cannula.

e. Comparison to Predicate Device

The Estech Percutaneous Insertion Dilator is substantially equivalent in intended use, design, materials, packaging and sterilization to the Maxxim Medical Vessel Dilator (K963388).

Both devices enlarge the opening in a blood vessel to permit the introduction of large diameter catheters or cannulae

The only differences between the predicate and the application device are that the predicate has a proximal hub that can be locked into the hub of some introducers and they have a different range of outside diameters. These design differences are not technological differences. These design differences do not introduce new issues of safety or efficacy.

Both devices are single use only and ethylene oxide sterilized.

Estech concludes that the devices are substantially equivalent.

f. Summary of Supporting Data

Biocompatibility analysis demonstrates that the kit components are in compliance with ISO 10993.

Manufacturing inspection and testing demonstrate that the kit meets its performance specifications and is therefore substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 24 2007

Endoscopic Technologies, Inc.
c/o Mr. Craig Coombs
President
Coombs Medical Device Consulting, Inc.
1193 Sherman Street
Alameda, CA 94501

Re: K070749
Trade/Device Name: ESTECH Percutaneous Dilator Insertion Kit
Regulation Number: 21 CFR 870.1310
Regulation Name: Vessel dilator for percutaneous catherization
Regulatory Class: Class II
Product Code: DRE
Dated: October 18, 2007
Received: October 12, 2007

Dear Mr. Coombs:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on the labeling regulation, please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (240) 276-3150, or at its Internet address http://www.fda.gov/cdrh.dsma/dsmamain.html.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Section 4: Indications for Use Statement

510(k) Number (if known): K070749

Device Name: ESTECH Percutaneous Dilator Insertion Kit

Indications For Use:

The ESTECH Percutaneous Insertion Dilator Kit is intended for use in surgical procedures to aid in percutaneous insertion of a catheter or cannula.

Prescription Use __X__ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of _____

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K070749